

K120378

Date: January 31, 2012

MAR 30 2012

510(k) Summary**3-1. 510(k) owner (submitter)**

- | | |
|---------------------------|---|
| 1) Name | KURARAY MEDICAL INC. |
| 2) Address | 1621 Sakazu, Kurashiki, Okayama 710-0801, Japan |
| 3) Contact person | Michio Takigawa
Quality Assurance Department |
| 4) Contact person in U.S. | Kiyoyuki Arikawa
KURARAY AMERICA INC.
600 Lexington Avenue, 26th Floor
New York, NY 10022
Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676
Fax: (212)-867-3543 |

3-2. Name of Device

- | | |
|-----------------------------|---|
| 1) Trade / Proprietary name | PANAVIA SA CEMENT Handmix |
| 2) Classification name | Dental cement
(21 CFR section 872.3275. Product code: EMA) |
| 3) Common name | Dental adhesive resin cement |

3-3. Predicate device

- | | |
|-----------------------|--|
| 1) CLEARFIL SA CEMENT | 510(k) Number: K081583
Product Code: EMA
21 CFR Section: 872.3275
Applicant: KURARAY MEDICAL INC. |
| 2) RelyX Unicem 2 | 510(k) Number: K100756
Product Code: EMA
21 CFR Section: 872.3275
Applicant: 3M ESPE AG DENTAL PRODUCTS |

3-4. Device Description

- 1) PANAVIA SA CEMENT Handmix is a dual-cure (light- and/or self-cure), radiopaque self-adhesive resin cement for porcelain, ceramic, composite resin and metal restorations. It is intended for the following indications:
 - (1) Cementation of crowns, bridges, inlays and onlays made of porcelain, ceramic, composite resin or metal
 - (2) Cementation of porcelain, ceramic, composite resin or metal restorations on implant abutments
 - (3) Cementation of metal cores, resin cores, metal posts or glass fiber posts
- 2) It is classified into dental cement (21 CFR section 872.3275, Product code: EMA) according to 21 CFR§872 since it is composed of various materials other than zinc oxide-eugenol.
- 3) Physical and mechanical properties of the subject device were evaluated according to ISO 4049: 2009 (Dentistry - Polymer-based restorative and materials). According to ISO 4049: 2009, the subject device is classified into the following:
 - Class 3: materials that are cured by the application of external energy and also have a self-curing mechanism present(This product contains the adhesive monomer. ISO 4049:2009 does not cover the polymer-based luting materials that have an adhesive component within the structure of the material. However, we tested referring to this standard.)

3-5. Substantial Equivalence Discussion

- 1) Intended uses
The INDICATIONS of the subject device were written up based on those of the predicate devices. Therefore, the intended purposes of the subject device are substantially the same as those of the predicate ones.
- 2) Chemical ingredients / Safety
All chemical ingredients of PANAVIA SA CEMENT Handmix are equivalent to those of the predicate device, CLEARFIL SA CEMENT.
Regarding the predicate device, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in U.S.
Therefore, we have concluded that the safety of the subject device can be guaranteed.
- 3) Effectiveness / Performance
PANAVIA SA CEMENT Handmix complies with all requirements of ISO 4049: 2009 as polymer-based restorative materials.
And also, the bond strength of the subject device is equivalent to that of the predicate devices.
Therefore, it can be said that its effectiveness has also been proved.

3-6. Biocompatibility

All the chemical ingredients of the subject device, PANAVIA SA CEMENT Handmix, are the same as those of the predicate device, CLEARFIL SA CEMENT, as shown on the tables of "7-4 Chemical ingredients": in "Section 7: Substantial Equivalence Discussion".
Regarding the predicate devices, there have not been any reported problems or recalls according to the post- market adverse event reporting requirements in U.S.
Therefore, we have concluded that the biological safety of the subject device can be guaranteed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Michio Takigawa
Manager
KURARAY MEDICAL Incorporation
Ote Center Bldg. 7F, 1-1-3, Otemachi
Chiyoda-ku
Japan 100-0004

MAR 30 2012

Re: K120378
Trade/Device Name: PANAVIA SA CEMENT Handmix
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: January 31, 2012
Received: February 8, 2012

Dear Mr. Takigawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: PANAVIA SA CEMENT Handmix

Indications for Use:

- [1] Cementation of crowns, bridges, inlays and onlays made of porcelain, ceramic, composite resin or metal
- [2] Cementation of porcelain, ceramic, composite resin or metal restorations on implant abutments
- [3] Cementation of metal cores, resin cores, metal posts or glass fiber posts

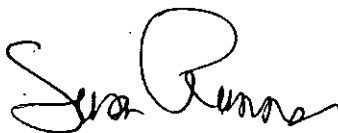
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use N/A
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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